510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR part 807.92.

Submitter: NovoSci™ Corp
2828 N. Crescent Ridge Dr.
The Woodlands, Texas 77381

Contact: LeAnn Latham
Regulatory Affairs Manager
Phone: 281-363-4949 ext. 234

Device trade name: NovoSci™ Ready System®

Common name: Extracorporeal Circuit

Classification name: Catheter, Cannula and Tubing, Vascular, Cardiopulmonary Bypass

Adaptor, Stopcock, Manifold, Fitting, Cardiopulmonary Bypass

Pump, Blood, Cardiopulmonary Bypass, Non-roller Type

Filter, Blood, Cardiopulmonary Bypass, Arterial line

Oxygenator, Cardiopulmonary Bypass

Reservoir, Blood, Cardiopulmonary Bypass

Classification: Class III
Panel: Cardiovascular (CV)
Product code: DWF, DTL, KFM, DTM, DTZ, DTN
Regulation Number: 870.4360

Predicate Device: Jostra MECC System
V-bag, V-box for vacuum assist.

Device Description:

The NovoSci™ Ready System® is a closed loop extracorporeal system providing circulatory, thermal and gas-exchange support for extracorporeal perfusion. The

K033270

NovoSci™ Ready System® is provided as a sterile system with a non-pyrogenic fluid pathway for single use only and is not to be re-sterilized by the user.

Indications for Use:

The NovoSci™ Ready System® is indicated for use in surgical procedures requiring extracorporeal circulation and gas exchange support for 6 hours or less.

Statement of Technological Characteristics Comparison:

The NovoSci™ Ready System® is substantially equivalent to the predicate devices.

Non-clinical testing

Biocompatibility, in-vitro and performance testing were performed to demonstrate equivalence. These tests included: blood damage, reservoir pressure drop, minimum operating volume, micro air, vacuum pressure, flow rate vs. vacuum.

Conclusions:

These data support that the NovoSci™ Ready System® is substantially equivalent in safety and efficacy to the currently marketed Jostra MECC System and V-bag, Vac box

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 13 2004

NovoSci™ Corp.
c/o Ms. LeAnn Latham
Regulatory Affairs Manager
2828 N. Crescent Ridge Drive
The Woodlands, TX 77381

Re: K033270
NovoSci™ Ready System®
Regulation Number: 21 CFR 870.4360
Regulation Name: Non-roller type cardiopulmonary bypass blood pump
Regulatory Class: Class III (three)
Product Code: KFM
Dated: December 18, 2003
Received: December 19, 2003

Dear Ms. Latham:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna R. Vochmer

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K033270

Device Name: NovoSci™ Ready System®

Indications For Use:

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Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vachon

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K033270